APR 2 9 2002

K013471

PAGE 1 OF 2

EXHIBIT 2

510(k) Summary of Safety and Effectiveness

E.S.W.L. Products, Inc.
1542 Barclay Blvd.
Buffalo Grove, IL 60089
USA
Tel 1+847-419-6844
Fax 1+847-419-6881
Contact: Christopher Nowacki, President

October 17, 2001

1. Identification of the Device:
   Proprietary-Trade Name: "Delta™ 2000" Series Lithotripter.
   Classification Name/Product Code: **78 LNS**
   Common/Usual Name: Extracorporeal Shock Wave Lithotripter

2. Equivalent legally marketed devices: Dornier Compact Alpha Lithotripter, K002929; EDAP Technomed Sonolith Praktis, K003529; Storz Modulith Lithotripter Model SLK, K010340.

3. Indications for Use (intended use) The Delta™ 2000 Series Lithotripter is intended to fragment urinary stones in the kidney (renal pelvis and renal calyces) and ureter (upper, middle, and lower ureter).

4. Description of the Device: The DELTA lithotripter utilizes well known spark gap technology. To generate a shock wave utilizing this method, an electrical discharge is created between two electrodes submerged in water. This sudden discharge of the enormous amount of energy lasts less than 1 microsecond. During this time an evaporation of water surrounding the gap between the electrodes occurs. The evaporation causes an instant expansion of vapor which produces a shock wave. In an extracorporeal lithotripter, the two wire electrodes are embedded in a plastic tube filled with insulating material. On one end of the tube the tips of the wire are bent towards each other with a small gap between them. A source of electrical energy is connected to each wire on the other end of this tubular structure. This electrode assembly is placed inside an ellipsoidal reflector in such a way that the gap between the two conductors coincides with the first focal point of the reflector. The reflector is filled with water and covered with a thin elastic membrane. After discharging the energy, reflected shock waves are transmitted to the second focal point through noncompressible medium, such as water in the reflector and in human tissue. The energy generated at the first focal point is recaptured at the second focal point of the ellipsoidal reflector with only minimal losses. When the second focal point is positioned on the treatment area such as the kidney stone inside the body, the repeated impact of the shock waves on the stone, at various energy levels, causes its disintegration.

K013471

PAGE 2 OF 2

5. Safety and Effectiveness, comparison to predicate device:

Comparison Areas	EDAP Technomed Sonolith Praktis, K003529	"Delta™ 2000" Series Lithotripter
Indications for use	Intended to fragment urinary stones in the kidney (renal pelvis and renal calyces) and ureter (upper, middle, and lower ureter).	SAME
Where used	Hospitals	SAME
Standards compliance	a. UL-2601 and IEC 60601 b. IEC 60601-2-36, "Medical electrical equipment - Part 2: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy" (1997). c. IEC 61846, "Ultrasonics - Pressure pulse lithotripters - Characteristics of fields" (1998). d. EMC: Compliance with IEC 60601-1-2 will be maintained, except during the triggering and generation cycle of the PRESSURE PULSE release	SAME
Technology	Extracorporeal shock wave, spark.	SAME.
Power Source	120 VAC 50-60~ 15 amp outlet	SAME

6. Conclusion: In all material respects, the "Delta™ 2000" Series Lithotripter is substantially equivalent to one or more products of similar description. Testing, certifications, and clinical experience demonstrates that the device is equivalent to the EDAP Technomed Sonolith Praktis, K003529, currently on the market. The "Delta™ 2000" Series Lithotripter meets the requirements of Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi, Document issued on August 9, 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 9 2002

E.S.W.L. Products, Inc.
c/o Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates, Inc.
P.O. Box 7007
DEERFIELD IL 60015

Re: K013471
Trade/Device Name: Delta™ 2000 Series Extracorporeal Lithotripter
Regulation Number: 21 CFR 876.5990
Regulation Name: Extracorporeal shock wave lithotripter
Regulatory Class: II
Product Code: 78 LNS
Dated: February 20, 2002
Received: February 21, 2002

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

10. Indications for Use

510(k) Number K013471

The Delta™ 2000 Series of Extracorporeal Lithotripter is intended to fragment urinary stones in the kidney (renal pelvis and renal calyces) and ureter (upper, middle, and lower ureter).

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013471